UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

SOTHINATHAN SINNATHURAI,
Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

NOVAVAX, INC.,
STANLEY C. ERCK,
GREGORY F. COVINO,
JOHN J. TRIZZINO and
GREGORY M. GLENN,

Defendants.

Civil Action No. TDC-21-2910

MEMORANDUM OPINION

In this class action against Defendant Novavax, Inc. ("Novavax") and several of its officers (collectively, "the Individual Defendants"), Plaintiffs allege violations of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78a-qq (2018) ("the Exchange Act"), and 17 C.F.R. § 240.10b-5 (2022) occurring during the time period from February 24, 2021 to October 19, 2021 ("the Class Period"). Pending before the Court is Defendants' Motion to Dismiss, which is fully briefed. Having reviewed the submitted materials, the Court finds that no hearing is necessary. *See* D. Md. Local R. 105.6. For the reasons set forth below, Defendants' Motion will be GRANTED IN PART and DENIED IN PART.

BACKGROUND

I. History of Novavax

Novavax is a biotechnology company headquartered in Gaithersburg, Maryland that focuses on the discovery, development, and commercialization of vaccines to prevent serious infectious diseases. Novavax has common stock that trades on the NASDAQ stock exchange. Defendant Stanley C. Erck has served as Novavax's President and Chief Executive Officer ("CEO") since April 2011 and as a member of Novavax's Board of Directors since 2009. Defendant Gregory F. Covino served as Novavax's Chief Financial Officer ("CFO"), as its Treasurer, and as an Executive Vice President ("EVP") from November 16, 2020 to April 12, 2021. Defendant John J. Trizzino served as Novavax's Interim CFO from April 12, 2021 to August 16, 2021. Trizzino also serves as Novavax's Chief Commercial Officer, Chief Business Officer, and as an EVP. Defendant Gregory M. Glenn has served as Novavax's President of Research and Development since March 2016.

Historically, Novavax has focused on manufacturing vaccines for novel viruses and infections. For example, prior to the COVID-19 pandemic, Novavax tried to develop vaccines for HIV, SARS, swine flu, and the Ebola virus. However, each of the vaccines either failed in testing or the epidemics faded out, such that there was reduced need for a vaccine. To date, Novavax has never brought a successful vaccine candidate to market.

Prior to the onset of the COVID-19 pandemic in early 2020, Novavax was facing significant financial hardship. In 2019, to avoid going out of business, Novavax sold all of its manufacturing facilities. As of January 2020, Novavax had only 150 employees and only enough cash to survive for another six months. Its shares traded at under $4.00 per share and had a total

market value of only $127 million. Novavax therefore was at risk of being delisted from the NASDAQ stock exchange.

II. COVID-19 Vaccine Development

The onset of the COVID-19 pandemic in early 2020 provided Novavax with an opportunity to revive itself by finally developing a vaccine and bringing it to market. On February 26, 2020, Novavax announced that it was developing a COVID-19 vaccine candidate known as NVX-CoV2373 ("the Novavax Vaccine" or "the Vaccine") using a proprietary nanoparticle technology. In a February 2021 report to the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations ("the House Committee on Energy and Commerce"), Trizzino stated, "[G]etting this vaccine in the arms of people . . . is our priority and singular goal right now. Our team continues to work non-stop to get NVXCoV2373 developed, authorized for use and ultimately delivered to vaccination clinics." Am. Compl. ¶ 267, ECF No. 56. Similarly, in its United States Securities and Exchange Commission ("SEC") Form 10-Q for the first quarter of 2021, Novavax stated that "[a]t the forefront of [its] pipeline is NVX-CoV2373." *Id.* ¶ 267. According to the Center for Financial Research and Analysis ("CFRA"), a market analyst, "the future financial success of [Novavax] and its ability to record a positive bottom-line result [was] highly dependent on successful approvals and rapid commercialization of its COVID-19 vaccine." *Id.* ¶ 55.

On June 4, 2020, Novavax entered into a contract with the United States Department of Defense ("DOD") under which it received $60 million in funding. According to the contract, Novavax was required to "establish within the United States large scale production" of one of the Novavax Vaccine's major components. *Id.* ¶ 57. The terms of the contract also provided that if Novavax was able to secure approval of the Novavax Vaccine from the United States Food and

Drug Administration ("FDA"), it was required to deliver 10 million doses to DOD by December 2020.

On July 7, 2020, Novavax joined Operation Warp Speed, the federal government program to facilitate the development, manufacturing, and distribution of COVID-19 vaccines and thus received $1.6 billion in funding to complete late-stage clinical development, including a Phase 3 clinical trial; establish a large-scale manufacturing process; and deliver 100 million doses of the Novavax Vaccine as early as the end of 2020. As part of the agreement, Novavax was required to demonstrate that it could rapidly set up large-scale manufacturing and transition into ongoing production, including the capability to stockpile and distribute large quantities of the Novavax Vaccine when needed.

Because Novavax did not have its own manufacturing facilities, it entered into agreements with other companies to manufacture and produce the Novavax Vaccine. For example, on July 23, 2020, Novavax entered into a contract with FUJIFILM Diosynth Biotechnologies ("FUJIFILM") to manufacture bulk drug substance for the Novavax Vaccine at FUJIFILM's facilities in College Station, Texas and Durham, North Carolina ("the Texas Facility" and "the North Carolina Facility," respectively). The Texas and North Carolina Facilities were the only two manufacturing facilities in the United States producing the antigen component of the Novavax Vaccine. As Trizzino stated in his February 2021 testimony before the House Committee on Energy and Commerce, the antigen produced at the Texas and North Carolina Facilities was a "critical component" of Novavax's U.S. supply chain. *Id.* ¶ 269.

Throughout the vaccine development and manufacturing process, Novavax was required to adhere strictly to FDA standards, including the FDA Current Good Manufacturing Practices ("cGMP") Regulations, which establish requirements to ensure proper design, monitoring, and

control of manufacturing processes and facilities. 21 C.F.R. §§ 210.1-211.208 (2022). Novavax's June 4, 2020 DOD contract specifically stated that Novavax was required to "manufacture enough bulk drug substance to produce ten million doses of vaccine drug product, all under current Good Manufacturing Practices and compatible with use in a late stage development clinical evaluation or Emergency Use Authorization." *Id.* ¶ 63. The contract also required that Novavax "ensure all quality control/assurance" adhered to "phase appropriate" cGMP Regulations to "ensure product quality and availability for use of the doses produced." *Id.*

Ultimately, Novavax sought to apply for and receive from the FDA Emergency Use Authorization ("EUA") for the Novavax Vaccine, which would permit the "introduction into interstate commerce" of a drug "intended for use in an actual or potential emergency" that is not "approved, licensed, or cleared for commercial distribution." 21 U.S.C. § 360bbb-3(a) (2018).

III. Manufacturing Concerns

Throughout the Class Period, Novavax consistently faced manufacturing and production problems, including: (1) repeated contamination outbreaks at its Texas and North Carolina Facilities; (2) the failure to meet FDA standards for the purity and potency levels of the Novavax Vaccine; (3) the failure to successfully scale up production of the Novavax Vaccine; and (4) disruption of supply chains. These problems caused repeated delays in Novavax's filing of an EUA application.

A. Contamination Incidents

Throughout the Class Period, Novavax experienced repeated contamination events at the Texas and North Carolina Facilities that required production to be shut down and prevented Novavax from achieving the levels of purity and potency required by the FDA.

1. The Texas Facility

In December 2020 or January 2021, the Texas Facility experienced its first contamination incident. According to Confidential Witness ("CW") 5, who was then FUJIFILM's Head of Technical Operations for Gene Therapy at the Texas Facility, this bacterial contamination was caused by an employee improperly reusing a plastic bag instead of discarding and replacing it as required by protocol. In February 2021 or March 2021, there was a second incident of contamination at the Texas Facility, this one caused by an employee reusing a single-use blade, in violation of standard operating procedure. According to CW 5, Novavax had supply chain problems that included difficulty obtaining the necessary number of these blades. According to CW 6, who at the time was FUJIFILM's Director of Manufacturing at the Texas Facility, there were two to three other contamination incidents at the Texas Facility, including one caused by a leak in a bag used as part of a bioreactor.

From March 15, 2021 to March 19, 2021, the FDA conducted an inspection of the Texas Facility, after which FDA officials met with the Texas Facility's Chief Operating Officer and other managers to flag various identified "items of concern," including that the facility had "sub optimal quality operations." Am. Compl. ¶ 98. On April 14, 2021, the FDA issued a formal 52-page inspection memorandum ("the FDA Texas Facility Report"), detailing issues reflecting the Texas Facility's inadequate quality control, contamination, and purity problems, including that:

(a) Contamination was discovered and not properly recorded and investigated, including microbial contamination that was discovered in January 2021.

(b) [There was a] [f]ailure to investigate, detect, and document appropriately a number of deviations, and . . . periodic review of deviation trending was not performed by the Quality Unit.

(c) [The] [c]leaning procedure for certain manufacturing areas was not always followed, including using disinfectants on surfaces in manufacturing areas

> that were not effective in inactivating or adequately removing microorganisms.
>
> (d) [There was a] [f]ailure to open "change controls" when appropriate.
>
> (e) Out-of-specification . . . investigation procedures were not always followed.
>
> (f) Warehouse areas used for storage of GMP materials were overcrowded and poorly organized.
>
> (g) [There was] inadequate and ineffective training of manufacturing workers due to [a] sharp increase in new hires.

Id. ¶ 100. The FDA concluded that "[q]uality oversight over manufacturing and testing operations [was] sub-optimal." *Id.* ¶ 101. After this inspection, the manufacturing at the Texas Facility was shut down from March 2021 until at least September 2021.

2. The North Carolina Facility

Contamination outbreaks also occurred at the North Carolina Facility, requiring entire batches of the Novavax Vaccine to be discarded. Between April 14, 2021 and April 21, 2021, the FDA conducted an inspection at the North Carolina Facility and then issued an FDA Form 483 identifying many quality-related problems, including:

> (a) Microbial control of the facility was inadequate [because] the facility's employees failed to investigate root causes and implement adequate corrective and preventative actions to control microbial contamination, as exemplified by the FDA learning from prior reports that microbial contamination . . . was recovered from over 50 monitoring sites—including in purification sites.
>
> (b) There was no comprehensive risk assessment conducted to evaluate cross-contamination of drug products, including where such drug products were manufactured in the same areas with shared product contact equipment.
>
> (c) The manufacturing process was not adequately monitored and/or controlled to ensure the quality of the drug substance was not adversely affected.
>
> (d) Written procedures for manufacturing processes were inadequate, including inadequate procedures for the "Purification" step.

(e) Discrepancies were not fully investigated to identify a root cause and corrective and preventative actions were not adequately implemented to prevent recurrence.

(f) Procedures of material management systems were not followed or were inadequate, which led to expired materials being found in the warehouse.

Id. ¶ 103.

The FDA raised concerns on other occasions as well. For example, CW 1, who was then Novavax's Manager of Regulatory Affairs for Chemistry, Manufacturing, and Controls, has asserted that in response to Novavax's Module 3 Quality reports—reports submitted to the FDA that contain drug and product information and data from the manufacturing sites—the FDA informed Novavax, by email to Director of Regulatory Affairs Kathleen Callahan, that the stability of the vaccine batches "wasn't going to cut it." *Id.* ¶ 104. According to CW 1, this and other FDA concerns were discussed during weekly meetings of Novavax's Regulatory Affairs team.

B. Purity and Potency Levels

Plaintiffs have alleged that throughout the Class Period, Novavax was unable to produce a vaccine that met certain FDA purity and potency criteria, which contributed to its failure to file an application for EUA. By the end of the Class Period in October 2021, Novavax was able to achieve only a 70 percent level of purity, below the 90 percent required by the FDA. Some batches of the Vaccine had purity levels as low as 30 percent. Similarly, according to CW 4, who was then the Novavax Senior Director of Clinical Operations, Novavax was "delayed in manufacturing" due to issues with "lesser potency" and the "stability" of the vaccines. *Id.* ¶ 84.

C. Failure to Scale Up Production

Plaintiffs also allege that Novavax was unable to scale up vaccine production and was thus unable to produce enough viable doses for use in clinical trials of the Novavax Vaccine, which contributed to delays in filing Novavax's EUA application. Specifically, CW 2, who was then a

Novavax Medical and Communications Publications Specialist, has stated that there were production delays because, as she learned from colleagues, Novavax was not efficient at producing vaccines at a scale necessary for mass production. CW 2 further alleged that as a result, Novavax struggled to produce enough proper vaccine doses for several clinical trials, including three smaller clinical trials in 2021, causing them to be delayed.

These scaling issues and delays were likely the result of the lack of experience of Novavax and FUJIFILM in producing a vaccine at this scale on an accelerated timeline. CW 4 reported that Novavax did not have a clinical development program, as is typically needed. According to CW 5, these scaling issues and associated delays were based in part on the fact that FUJIFILM hired many new employees with little or no previous vaccine manufacturing experience. CW 8, who was then a FUJIFILM Quality Control Analyst at the North Carolina Facility, has reported that delays were the result of the need to alter the process "almost constantly" and sometimes skipping certain steps in order to pursue an accelerated production timeline. *Id.* ¶ 92.

D. Supply Chain Disruptions

Finally, Novavax experienced supply chain disruptions that further delayed its efforts to file an EUA application with the FDA. According to CW 6, domestic supply constraints and difficulty obtaining certain materials "were always a struggle." *Id.* ¶ 93. Similarly, CW 7, who was a FUJIFILM Quality Assurance Manager at the North Carolina Facility, has stated that throughout the development of the Novavax Vaccine, Novavax had difficulty procuring needed components such as filters and resin used in the vaccine manufacturing process. The North Carolina Facility also had difficulty obtaining rubber silicone hoses and raw materials. CW 5 has stated that global supply chain issues caused difficulties in acquiring the necessary number of different components, such as blades that were used in the manufacturing process. CW 3, a former

Novavax Laboratory Technician, has asserted that Novavax's work was slowed down by delays in acquiring certain raw materials "needed from different companies to use their machines." *Id.* ¶ 95.

IV. Knowledge of Manufacturing Problems

Plaintiffs allege that Novavax generally and the Individual Defendants specifically were aware of the manufacturing problems related to contamination, purity, potency, scalability, and the supply chain, particularly the issues at the Texas and North Carolina Facilities. Plaintiffs allege that Novavax was aware of the manufacturing problems at the Texas Facility because the FDA Texas Facility Report specifically references that FUJIFILM was required by its agreement with Novavax to notify Novavax of the identified problems within two business days. CW 5 has asserted that Novavax had two onsite employees at the Texas Facility, Technology Transfer Engineer Patrick Hash and Contractor Elizabeth Wang, and that CW 5 and CW 6 communicated with them "every single day" regarding manufacturing and the results of quality checks, which were conducted every 24 to 48 hours. *Id.* ¶¶ 108, 110. Specifically, CW 5 has stated that the Novavax employees were notified of each contamination issue that occurred during the Class Period, that Hash participated in the investigations into the contaminations, and that Hash communicated information about the contaminations and delays to Novavax headquarters on a daily basis. According to CW 6, she participated in Zoom calls "every day" with Novavax's onsite employees, a Novavax employee at Novavax's headquarters, and other Novavax employees from different departments and that these Novavax personnel "knew everything" that FUJIFILM was doing at the Texas Facility. *Id.* ¶ 110.

As for the North Carolina Facility, CW 7 has stated that Novavax had an employee onsite at least weekly and that any contamination or other issues were regularly communicated to

Novavax. According to CW 7, Novavax's engagement in the manufacturing was more extensive than that of any other FUJIFILM client she had encountered, as Novavax was involved with "everything" and was "driving" the way in which FUJIFILM manufactured the product. *Id.* ¶ 112. Moreover, all testing results were communicated to Novavax through a "batch record." *Id.*

Plaintiffs allege that Novavax was aware of the supply chain problems because, as CW 3 has stated, at times Novavax addressed difficulties obtaining required materials by trying to make the materials itself or by trying to use different materials. Relatedly, CW 7 asserted that when FUJIFILM changed the manufacturing materials because of supply chain issues, Novavax was required to approve all such changes.

As for the issues with potency and purity, which occurred "off and on" in 2021, CW 4 reported that they were presented to a "broad group" at Novavax, including Vice President of Clinical Operations Patty Reed and Chief Medical Officer Filip Dubovsky, as well as "everyone" who reported to Dubovsky. *Id.* ¶ 85. Novavax employees from Quality Assurance, Regulatory, and other departments were also part of conference calls at which these issues were discussed.

Plaintiffs allege that Defendants were aware of the problems related to scaling up production based on CW 4's assertions that when production issues resulted in problems getting a clinical trial started, they were reported to Dubovsky and Erck. Specifically, manufacturing issues were brought to Dubovsky's attention, Dubovsky then discussed the issues with Erck, Erck then discussed the issues with Glenn, and Erck or Glenn sometimes brought the issues to the attention of the Board of Directors.

Plaintiffs also allege that Erck was directly involved in the activities relating to the Novavax Vaccine and was thus aware of the regulatory delays and manufacturing problems. For example, Erck held company-wide meetings related to the Novavax Vaccine that included

question-and-answer ("Q&A") sessions with employees. According to CW 1, the Q&A sessions included discussions about employees' concerns about Novavax's "manufacturing capabilities" and whether Novavax would "be able to get [its] stability information stabilized." *Id.* ¶ 116. CW 2 has stated that at these meetings, Erck discussed the topic of seeking regulatory approval. According to CW 1, Erck had access to the Module 3 Quality reports, submitted by Novavax to the FDA, which contained drug and product information and data from the manufacturing sites.

Finally, Plaintiffs allege that Novavax was necessarily aware of the manufacturing problems because the cGMP Regulations effectively required it to be directly involved in the manufacturing processes and stay apprised of issues arising at manufacturing facilities. For example, the cGMP Regulations required Novavax to establish a "quality control unit" that had responsibility for approving or rejecting "all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product" and for approving or rejecting all "drug products manufactured, processed, packed, or held under contract by another company." *Id.* (quoting 21 C.F.R. §§ 211.22(a), (c)). The cGMP Regulations also required Novavax to establish procedures to ensure that the "responsible officials" of Novavax were "notified in writing of any investigations conducted under §§ 211.198, 211.204, or 211.208 of [the] regulations, any recalls, reports of inspectional observations issued by the [FDA], or any regulatory actions relating to good manufacturing practices brought by the [FDA]." *Id.* ¶ 71 (quoting 21 C.F.R. § 211.180(f)). This requirement stood even if Novavax was "not personally involved in or immediately aware of such actions." *Id.* (quoting 21 C.F.R. § 211.180(f)).

The cGMP Regulations also required Novavax to maintain laboratory records that included "complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results

of tests and how the results compare with established standards." *Id.* ¶ 72 (quoting 21 C.F.R. § 211.194(a)). Lastly, the cGMP Regulations required Novavax to maintain and follow written procedures to prevent "objectionable microorganisms in drug products" and "the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products." *Id.* ¶ 73 (quoting 21 C.F.R. §§ 211.113, 211.56(c)).

V. False Statements and Material Omissions

Plaintiffs have alleged in the Amended Complaint that in light of Novavax's awareness of these manufacturing obstacles relating to contamination, purity and potency levels, scaling, and the supply chain, Defendants made ten specific false or misleading statements or omissions of material fact relating to these problems, as identified below in boldface, that violate the Exchange Act.

Plaintiffs first focus on a statement on February 24, 2021 that they claim constitutes a reassurance to investors that Novavax was complying with FDA requirements. During an interview with *The Washington Post* to discuss Novavax's regulatory timeline for its EUA application, after discussing clinical trials in the United Kingdom, Glenn stated:

> But one thing I would say is the U.K. data is very good. We expect to propose to the FDA that this data could be used as a basis for licensure. We'll see. That trial and the South African trial are all conducted in a way that the FDA will take that data seriously and the U.K. potentially as what we call the "pivotal data." **That is, we lined up—FDA gave advice on how to do a trial, what success means, and that really was accepted by the world, if you will, and so we're aligned up with those success criteria in all of our trials.**

Id. ¶ 120; Joint Record ("J.R.") 96–97, ECF No. 71.

Plaintiffs allege five false statements or material omissions arising from a May 10, 2021 earnings call. On that date, *The Washington Post* reported that Novavax's EUA "filing was delayed by manufacturing regulatory issues, until June at the earliest." Am. Compl. ¶ 126. The

same day, Novavax hosted an earnings call with investors and analysts to discuss Novavax's first quarter 2021 financial and operational results. During the call, Novavax confirmed that it was unlikely to seek an EUA from the FDA for the Novavax Vaccine for use in the United States until July 2021 at the earliest, which would be the third quarter of 2021. As part of the call, however, Erck made the following statements to reassure investors that the causes of these regulatory delays had been resolved:

> 1. Our timetable for regulatory filings, we know that we're delayed from where we thought we'd be at this point. But now we're giving guidance that **nearly all of the major challenges have been overcome** and we can clearly see the light at the end of the tunnel.
>
> 2. Today, our global supply chain now spans over 10 countries **with all of our manufacturing sites producing GMP material at scale.** I think we've done a remarkable job of standing up manufacturing in these multiple plants across the globe.
>
> 3. **I'm happy to report that we have got to the point where we've successfully manufactured our drug substance, a recombinant protein nanoparticle, at commercial scale in each of these plants.** The drug substance production is the most complicated step in the overall manufacturing processes.
>
> 4. And so I think it probably took a little longer than we expected to get a potency assay that was worked across—told the same story across all the sites. **But I'm happy to say we did. We've crossed that bridge. We're—we made a big breakthrough there and we're now racing towards validating everything and putting it into a package.**
>
> 5. [E]very quarter gets more data pointing to a successful vaccine, we're getting close to the end, and—which is really the beginning for us and that's what we're all racing to do. **I think we've eliminated all of the serious hurdles to getting—risk hurdles to getting to where we need to be to get an improved vaccine.** And so we're excited about that and we look forward to shipping our first product.

Id. ¶¶ 178–81; J.R. 360–61, 366. Following the announcement of the delay, the Novavax stock price fell 8.81 percent on May 10, 2021 and an additional 13.91 percent on May 11, 2021.

Plaintiffs allege that the stock price would have fallen even further absent these allegedly false statements or material omissions designed to reassure investors.

Plaintiffs allege an additional false statement or material omission by Erck during a June 14, 2021 clinical update call with investors:

> These trials taught us a lot about our vaccine and from the early clinical data and even the preclinical work before that, we were encouraged about the potential of NVX-CoV2373 to play a significant role in combatting the global COVID pandemic. **With each analysis, our trials proved that we are on the right track. And today, with safety and efficacy that are consistent across all studies, our PREVENT-19 results reaffirm our strong belief in [the Novavax Vaccine].**

Am. Compl. ¶ 190; J.R. 377.

The next alleged false statement or material omission occurred on August 5, 2021 after Novavax reported in a press release that it was at that point planning to file its application for an EUA in the fourth quarter of 2021, rather than the third quarter as previously projected. That same day, in an interview with *Reuters*, Erck stated, **"We appear to have got past (certain) supply issues and are now being able to produce at scale."** Am. Compl. ¶ 147. Plaintiffs allege that this statement was designed to "conceal the full truth regarding the underlying problems Novavax faced." *Id.* Following the announcement of the additional delay, the Novavax stock price fell 19.61 percent on August 6, 2021.

Plaintiffs also identify an alleged false statement or material omission that occurred during the Devex United Nations General Assembly ("UNGA") 76th Annual Conference on September 21, 2021, when Trizzino responded to a question about "transparency on the part of manufacturers" by stating, "This transparency is important. **And we've been extremely transparent across multiple fronts. All of our clinical data has been shared very quickly."** *Id.* ¶ 202; J.R. 572.

The final alleged false statement or material omission arises from September 29, 2021 Cantor Fitzgerald Global Healthcare Conference during which Trizzino reassured investors that certain problems were resolved:

> But the combination of our recombinant protein nanoparticle structure, the particle structure of our Matrix adjuvant presented some challenges in those assays, **which have now been resolved.** They've—both of those release assays have been validated.

Am. Compl. ¶ 204; J.R. 846.

VI. Stock Sales

The Amended Complaint also alleges that during the Class Period, the Individual Defendants engaged in sales of their own stock in Novavax in advance of public announcements of adverse information about the development and progress of the Novavax Vaccine. In mid-to-late April 2021, Glenn sold over 8,000 shares of Novavax stock and received over $1.6 million in proceeds. On May 5, 2021 and May 7, 2021, Trizzino sold over 3,000 shares of Novavax stock, generating almost $600,000 in proceeds. On May 10, 2021, after the announcement that Novavax would be delaying its filing of an EUA application until the third quarter of 2021, Novavax's share price declined by 8.81 percent.

In July 2021, Erck sold over 100,000 shares of Novavax stock and received over $22.5 million in proceeds. That same month, Glenn sold over 8,000 shares of stock and received more than $1.5 million in proceeds. On August 5, 2021, after the announcement that Novavax was further delayed in filing its EUA application until the fourth quarter of 2021, Novavax's share price declined by 19.61 percent.

When the Individual Defendants trading of Novavax Stock during the Class Period of February 24, 2021 to October 19, 2021 is compared to the same time period in 2020 ("the Control Period"), Erck, Trizzino, and Glenn collectively increased their total stock sales by over 33 percent,

from 247,326 shares sold during the Control Period to 329,505 shares sold during the Class Period. Collectively, the proceeds from the Individual Defendants' sales of Novavax stock increased by over 118 percent, from $29,896,044 during the Control Period to $65,195,024 during the Class Period.

Erck individually sold almost five times as many shares during the Class Period as compared to during the Control Period. Indeed, in July 2020, one year before his significant stock sales in July 2021, Erck sold no Novavax stock. Erck's proceeds from Novavax sales increased by more than 750 percent—from $4,549,253 during the Control Period to $38,672,789 during the Class Period.

VII. *Politico* Article

On October 19, 2021, *Politico* published an article entitled, "'They rushed the process': Vaccine maker's woes hamper global inoculation campaign," which revealed the underlying and undisclosed manufacturing problems that had been preventing Novavax from filing its EUA application with the FDA and alerted investors for the first time that Novavax's timeline for approval was still another year away. Am. Compl. ¶ 156. Specifically, the article reported that Novavax faced "significant hurdles in proving it can manufacture a shot that meets regulators' quality standards." *Id.* ¶ 157. For example, it detailed Novavax's failure to reach anywhere close to the 90 percent purity level required by the FDA. It also stated that senior officials on Operation Warp Speed repeatedly warned Novavax that it risked running into problems in scaling up manufacturing of the Novavax Vaccine and were worried that Novavax would have difficulty ensuring that it consistently met the FDA's rigorous quality standards once it went into mass production.

The article further stated that Novavax's issues were "more concerning than previously understood" and that Novavax could take until the end of 2022 to resolve its manufacturing problems and secure regulatory authorizations and approvals. *Id.* On October 20, 2021, the day after the publication of this article, Novavax's stock price fell 14.76 percent.

On November 12, 2021, the initial Complaint in this action was filed as a class action on behalf of all person and entities which purchased publicly traded common stock of Novavax during the Class Period. On January 26, 2022, David Truong, Nuggehalli Balmukund Nandkumar, and Jeffrey A. Gabbert were named as Lead Plaintiffs. ECF No. 47. In the currently operative Amended Complaint, Plaintiffs allege that Defendants knowingly made the above-referenced false statements and omissions of material fact to investors regarding Novavax's ability to obtain EUA, in violation of Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b), 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 10b-5.

DISCUSSION

In their Motion, Defendants seek dismissal under Federal Rule of Civil Procedure 12(b)(6), and pursuant to the heightened pleading standard of the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 ("PSLRA"), on the grounds that the 109-page Amended Complaint fails to state a plausible claim for relief under the Exchange Act because Plaintiffs have not identified false statements or material omissions in public statements and have not plausibly alleged that Defendants acted with the requisite scienter.

I. Legal Standards

To defeat a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the complaint must allege enough facts to state a plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is plausible when the facts pleaded allow "the court to draw the

reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Legal conclusions or conclusory statements do not suffice. *Id.* The Court must examine the complaint as a whole, consider the factual allegations in the complaint as true, and construe the factual allegations in the light most favorable to the plaintiff. *Albright v. Oliver*, 510 U.S. 266, 268 (1994); *Lambeth v. Bd. of Comm'rs of Davidson Cnty.*, 407 F.3d 266, 268 (4th Cir. 2005).

Ordinarily on a Rule 12(b)(6) motion, the Court considers only the allegations in the complaint and its attachments. Fed. R. Civ. P. 12(d); *Sec'y of State for Defence v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007). Courts are permitted to consider documents attached to a motion to dismiss "when the document is integral to and explicitly relied on in the complaint, and when the plaintiffs do not challenge the document's authenticity." *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 606–07 (4th Cir. 2015) (quoting *Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004)). Here, Defendants have submitted, within a Joint Record, transcripts or exhibits containing the specific alleged actionable statements, consisting of Exhibits 2, 7, 9, 11, 12, 13, and 18. Where these documents are integral to the complaint and Plaintiffs have not objected to their consideration, the Court will consider them. *See Sec'y of State for Defence*, 484 F.3d at 705; *Zak*, 780 F.3d at 606–07. The Court will not, however, consider the remaining exhibits within the Joint Record. *See Zak*, 780 F.3d at 607 (finding that the district court erred in considering SEC filings relating to stock sales at the motion-to-dismiss stage because the filings were not integral to the complaint).

II. Exchange Act

In their Amended Complaint, Plaintiffs have alleged violations of Sections 10(b) and 20(a) of the Exchange Act based on various allegedly false statements or omissions of material fact made by Defendants during the Class Period. In addressing the Motion, the Court will first discuss the

controlling legal standards for claims under Sections 10(b) and 20(a) and then assess whether Plaintiffs have adequately stated a plausible claim for relief.

Section 10(b) of the Exchange Act makes it "unlawful for any person, directly or indirectly" to use "in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). One such SEC rule is Rule 10b-5, which states, as relevant here, that it is unlawful for "any person" "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5.

Section 20(a), meanwhile, establishes liability for each "person who, directly or indirectly, controls any person liable" under the Exchange Act and its applicable regulations. 15 U.S.C. § 78t(a). Because Plaintiffs' Section 20(a) claim is premised on their Section 10(b) claim, and Defendants do not argue that it fails for reasons beyond the Section 10(b) claim, the Court will review the Exchange Act claims collectively under the standards applicable to Section 10(b) claims. *See Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 628 (4th Cir. 2008) (finding that where plaintiffs' claims under Sections 20(a) of the Exchange Act were "derivative of" their Section 10(b) and Rule 10b-5 claims, dismissal of the latter claims meant that dismissal of the Section 20(a) claims was proper).

An Exchange Act claim under Section 10(b) and Rule 10b-5 requires: (1) that the defendant made a false or misleading statement or omission of material fact; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase of a sale or security; (4)

reliance on the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011); *Singer v. Reali*, 883 F.3d 425, 438 (4th Cir. 2018). Because Defendants argue only that Plaintiffs' claims do not satisfy the first two elements—a material false or misleading statement or omission and scienter—the Court will address only these elements.

Federal Rule of Civil Procedure 9(b) and the PSLRA subject claims under Section 10(b) to heightened pleading standards. Rule 9(b) requires that, when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The PSLRA requires that in a private securities fraud action, for each allegation of a false or misleading statement or omission of a material fact, the complaint must "specify each statement alleged to have been misleading," "state the reason or reasons why the statement is misleading," and "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. §§ 78u-4(b)(1)(B), (b)(2)(A).

III. False Statements or Omissions of Material Fact

To prevail under Section 10(b), a plaintiff must show that the defendant made a statement or omission that "was *misleading* as to a *material* fact." *Matrixx Initiatives, Inc.*, 563 U.S. at 38 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)). For an omitted fact to be material, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Paradise Wire & Cable Defined Benefit Pension Plan v. Weil*, 918 F.3d 312, 318 (4th Cir. 2019) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). "[V]ague statements" consisting of "commonplace commercial puffery" are not material. *Raab v. Gen.*

Physics Corp., 4 F.3d 286, 289–90 & n.1 (4th Cir. 1993); *Howard v. Haddad*, 962 F.2d 328, 331 (4th Cir. 1992) ("[P]uffery . . . lacks the materiality essential to securities fraud allegations.").

In total, the Amended Complaint alleges ten different false statements or omissions of material fact in support of the Exchange Act claims. The Court will address each in turn.

A. February 24, 2021 *Washington Post* Interview

Plaintiffs allege that, in a February 24, 2021 *Washington Post* interview, Glenn made materially false or misleading statements or omissions when he asserted that Novavax's vaccine standards were "aligned" with the FDA's standards. Am. Compl. ¶¶ 120, 168. Specifically, the interviewer asked Glenn about the timing and conditions under which clinical trials would progress to the point of supporting an EUA application to the FDA:

> So, I know that you said quarter two is sort of the aim for when you would apply to FDA for emergency use authorization, but can you be a little more specific about that? And I ask because there was a lot of talk last fall about how much time needs to lapse between the time when the trial is fully enrolled and how much time the recipients of either the placebo or the vaccine are observed and how many cases you need to—of coronavirus you need to see. Can you talk about that a little bit in terms of, I guess, the timing or the number of cases you need to see and when you'll be able to know that, okay, now we can go ahead and apply to FDA?

J.R. 96. In response, Glenn stated:

> That's a great question. So, let me just walk you through how [it] works. We give people the vaccine regimen, and then we start looking for whether or not they have infection a week after their second dose, so Day 28. And then, essentially, we're waiting to see—people are out living their lives—waiting to see who gets infected and counting cases. So, we don't really control the timing.
>
> We are in a situation where there's a lot of disease, and also, we're in a situation where the net, if you will, for capturing diseases is very big. So, 30,000 people is what we call "overpowered." I would say in South Africa and the U.K., once we started into that period where people could be a case, had gotten their doses, and now were in the right time frame, it took us about six weeks to actually get—accrue—the number of cases we needed.
>
> So then once you know that—and so we don't know that. We get told by somebody who could—because we don't want to be unblinded in any way. Once we're told

> that, then—in the case of the U.S., 72 cases we're looking for—then they will push a button, and that will start to—they'll look at the data in a big database, clean it up, push a button, and we'll know. So, the timing is, frankly, uncertain, and it's one of those issues we're facing with all the trials. But one thing I would say is the U.K. data is very good. We expect to propose to the FDA that this data could be used as a basis for licensure. We'll see. That trial and the South African trial are all conducted in a way that the FDA will take that data seriously and the U.K. potentially as what we call the "pivotal data." **That is, we lined up—FDA gave advice on how to do a trial, what success means, and that really was accepted by the world, if you will, and so we're aligned up with those success criteria in all of our trials.**

J.R. 97. Plaintiffs allege that the bolded language above was false or misleading because at the time, Novavax was "in reality not aligned with FDA criteria needed to successfully manufacture and produce NVX-CoV2373," Am. Compl. ¶ 168, because it was unable to achieve the FDA's purity and potency requirements; was experiencing rampant contamination in its manufacturing facilities such that it was unable to successfully scale up production; and its manufacturing process was experiencing supply chain disruptions.

Even if Novavax was experiencing all of these problems, Glenn's statement that Novavax was "aligned up with those success criteria in all of [its] trials," on its face, relates to alignment with FDA standards for achieving successful clinical trials. This conclusion is bolstered by the fact that the statement immediately followed a discussion of clinical trials in the United Kingdom and South Africa in which Glenn noted that they were "conducted in a way that the FDA will take that data seriously." J.R. 97. However, Plaintiffs have alleged no specific facts to demonstrate that Novavax's clinical trials were noncompliant with FDA criteria for deeming a trial successful. All of Plaintiffs' allegations of non-compliance with FDA standards relate to manufacturing processes, which were not the subject of the conversation or Glenn's statement. They also have failed to allege any specific facts about the U.K. and South Africa clinical trials that would demonstrate that Glenn's statement was false or misleading. The Court therefore finds that the

allegations do not support the conclusion that through this statement, Glenn made a false statement or omission of material fact that could support Plaintiffs' Exchange Act claims.

B. May 10, 2021 Earnings Call

Five of the allegedly false or misleading statements or omissions of material fact are based on statements made in the May 10, 2021 earnings call. During that session, Erck discussed with investors the timeline for seeking regulatory approval of the Novavax vaccine and provided information relating to Novavax's manufacturing capabilities:

> Now I'd like to talk about the near and midterm focus of the company. And I'd like to start by addressing the questions that we get asked every single day with the goal of updating our guidance for the short term. First question we always get is when can we expect to see the results from the U.S. Phase III efficacy trial? The second is what is the timetable of regulatory filings in the various parts of the world? And the third is what is the trajectory for scaling up our manufacturing on a global basis.
>
> * * *
>
> Our timetable for regulatory filings, we know that we're delayed from where we thought we'd be at this point. **But now we're giving guidance that nearly all of the major challenges have been overcome and we can clearly see the light at the end of the tunnel.** All facilities in our network have already demonstrated the ability to manufacture commercial scale GMP material. The filing timetable depends on completing the final phases of qualification and validation of the assays that are needed to complete the demonstration of process consistency and to subsequently finalize the reports for regulatory filing.
>
> It has been a massive effort and has depende[d] on our global manufacturing partners to help us accumulate a suitable data package. And not surprisingly, it is currently the top priority of the company. It is not likely that we'll finish this work in time to submit by the end of June, so I'm changing our guidance to reflect that we expect to complete our regulatory filings in the third quarter. We are planning multiple filings that will be made with the U.S. FDA, the U.K. MHRA and with the EU EMA as soon as our data packages are complete.

J.R. 360–61.

As to manufacturing, Erck stated:

Let me next discuss the current state of our manufacturing and our anticipated capacity as we look to the remainder of the year. Please turn to Slide 20. On our last earnings call, we discussed the significant strides taken in 2020 to build out our global supply chain as seen on our global supply chain map. Some of the key manufacturing developments included reaching an agreement in principle with GSK to support fill and finish manufacturing of up to 60 million doses for use in the U.K., establishing manufacturing capabilities in Canada through our memorandum of understanding with the Canadian government to produce 2373 at the National Research Council's Biologics Manufacturing Center, finalizing exclusive license agreements with both Takeda and SK Bioscience in Japan and South Korea respectively.

Today, our global supply chain now spans over 10 countries with all of our manufacturing sites producing GMP material at scale. I think we've done a remarkable job of standing up manufacturing in these multiple plants across the globe. **I'm happy to report that we have got to the point where we've successfully manufactured our drug substance, a recombinant protein nanoparticle, at commercial scale in each of these plants.** The drug substance production is the most complicated step in the overall manufacturing processes.

Our guidance has been that we would be at full operating cadence by the end of the third quarter. As has been fairly widely reported, we are having difficulty getting to that point due to a global shortage of a few raw materials, including a shortage of 2,000-liter bags, depth filters, which are used in the purification process and then growth media. As closely as we try to manage these materials, we have been running into shortages that [have caused] us to delay production runs.

Our expectation is that our suppliers are adding sufficient capacity such that we will be operating at full capacity, but likely not until the fourth quarter. We expect we will be at full capacity throughout 2022 and beyond. The impact on us will be a somewhat slower rollout on product approval, but not dramatically. We are building inventory of our drug substance and the adjuvant as we speak. We have tens of millions of doses made already and will continue to produce approximately 100 million doses per month by the end of the third quarter. These will be ready to go . . . when we get our regulatory authorizations.

J.R. 361.

Later, in the question-and-answer portion of the call, Erck provide the following responses:

QUESTION: So maybe just, Stan, starting from the nonclinical CMC manufacturing components of the submission, are you able to comment on what might be these sort of things that are causing the holdup? Is it just process

> coordinating between the different sites? Or are there any specific issues around any particular assay? So if you're able to comment on that, that would be great.
>
> ERCK: No. I mean, and part of it has to do with manufacturing at different sites and showing comparability between the processes and the actual end product between the different sites. And you have to develop assays that can follow those. And so I think it probably took a little longer than we expected to get a potency assay that was worked across—told the same story across all the sites. **But I'm happy to say we did. We've crossed that bridge. We're—we made a big breakthrough there and we're now racing towards validating everything and putting it into a package.**

J.R. 366.

In his closing remarks at the end of the session, Erck stated:

> [E]very quarter gets more data pointing to a successful vaccine, we're getting close to the end, and—which is really the beginning for us and that's what we're all racing to do. **I think we've eliminated all of the serious hurdles to getting—risk hurdles to getting to where we need to be to get an improved vaccine.** And so we're excited about that and we look forward to shipping our first product. Thank you.

Am. Compl. ¶ 128–31; J.R. 366.

1. False Statements

In the Amended Complaint, Plaintiffs have asserted that the bolded statements marked above were false or misleading statements or resulted in material omissions. Plaintiffs have plausibly alleged that one of these statements, "Today, our global supply chain now spans over 10 countries with all of our manufacturing sites producing GMP material at scale," was demonstrably false when made. J.R. 361. As alleged in the Amended Complaint, multiple CWs have stated that manufacturing at the Texas Facility was shut down as of May 10, 2021, with one stating that the shutdown lasted from March 2021 to at least September 2021. Accordingly, the Texas Facility could not have been "producing GMP material at scale" at that time. J.R. 361.

However, Erck's subsequent statement within the same discussion, "I'm happy to report that we have got to the point where we've successfully manufactured our drug substance, a

recombinant protein nanoparticle, at commercial scale in each of these plants," J.R. 361, has not been plausibly alleged to be materially false or misleading. Although the manufacturing at the Texas Facility was shut down at that time, Plaintiffs have not alleged facts that would demonstrate that Novavax had not previously manufactured the recombinant protein nanoparticle at commercial scale in the Texas Facility. Nor have they alleged facts showing that the claim that such production had occurred at each of Novavax's other plants was untrue. Thus, Plaintiffs have not sufficiently alleged that this specific statement is materially false or misleading.

2. Material Omissions

Plaintiffs have alleged that the remaining identified statements from the May 10, 2021 earnings call demonstrate that Erck engaged in misleading omissions of material fact by failing to acknowledge, within those discussions, the significant manufacturing and production difficulties that Novavax then faced that hindered its ability to gain approval of, and engage in the mass production of, the Novavax Vaccine.

In several instances, the United States Court of Appeals for the Fourth Circuit has found that even in the absence of a specific false statement, when a company officer made statements giving a positive impression of the company's prospects, the failure to disclose related adverse information could constitute a material omission under the Exchange Act. For example, in *Ottman v. Hanger Orthopedic Group, Inc.*, 353 F.3d 338 (4th Cir. 2003), shareholders of defendant Hanger Orthopedic Group, Inc. ("Hanger") alleged material omissions when, following Hanger's acquisition of another company, NovaCare Orthotics & Prosthetics ("NovaCare"), Hanger officers made "mostly positive comments" regarding the integration during a call with investors, but they did not fully disclose that there had been a reduction in referral business from rehabilitation clinics due to the acquisition. *Id.* at 341–42. The court held that the plaintiffs sufficiently pleaded that

under the circumstances, the defendants had a "duty to disclose the lower percentage of patient referrals," and that the failure to do so constituted a material omission that significantly impacted Hanger's financial results. *Id.* at 352.

In *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597 (4th Cir. 2015), shareholders of the defendant company, Chelsea, alleged that the defendants made materially misleading statements and omissions about the development and likelihood of FDA approval for a new drug, Northera. *Id.* at 600–01. Although in order to grant approval, the FDA generally required the completion of two clinical trials that met their "primary endpoint," only one of the company's studies did so, and that study involved a treatment period of only a single week. *Id.* at 609. Nevertheless, Chelsea announced during a meeting that the FDA had "agreed" that Chelsea's new drug application could be submitted based on the single study, and its CEO stated during an investor call that the result of the meeting was a "successful outcome" that "reflected the strength of the data" generated by Chelsea's drug development program, and "mark[ed] a significant step forward for Chelsea." *Id.* at 602, 609. Other officers stated that Chelsea was "very pleased" with the FDA's responses to Chelsea's questions about its application and supporting data. *Id.* at 602–03. Later, although an FDA staff member drafted a briefing document that recommended against approval of Northera, Chelsea issued a press release stating that the document reflected that "several lines of inquiry . . . [had] emerged as significant components of the benefit-risk analysis of Northera," including that Chelsea's drug development program "may not adequately establish a durable treatment effect as a result of the short duration of" the trials, without disclosing that the FDA staff had recommended disapproval. *Id.* at 603, 610. The Fourth Circuit held that in the context of the statements that Chelsea "affirmatively elected to make," the plaintiffs had successfully alleged that the defendants "knowingly or recklessly misled investors by failing to

disclose critical information received from the FDA during the new drug application process, while releasing damaging information that they knew was incomplete." *Id.* at 609–10.

Likewise, in *Singer v. Reali*, 883 F.3d 425 (4th Cir. 2018), the Fourth Circuit held that shareholders of TranS1, Inc., a medical device company, had successfully alleged violations of the Exchange Act based on material omissions when the company failed to disclose that it was coaching surgeons to enter an incorrect billing code in order to fraudulently obtain reimbursement from insurers and government-funded healthcare programs for the use of the company's system for conducting surgery to treat degenerative disc disease. *Id.* at 428–29. Because the company made public statements to investment analysts that it was assisting surgeons in obtaining "appropriate reimbursement for [its] procedure" and that there would not be "any significant headwind" associated with the procedure codes, the court held that, "by choosing to speak about its reimbursement practices, the company possessed a duty to disclose its alleged illegal conduct." *Id.* at 442.

Here, Plaintiffs allege a material omission based on the statement, "But now we're giving guidance that nearly all of the major challenges have been overcome and we can clearly see the light at the end of the tunnel," which was made during Erck's discussion of Novavax's "timetable for regulatory filings." J.R. 360. Plaintiffs also allege material omissions relating to two statements made in the context of discussing Novavax's progress in "scaling up [its] manufacturing on a global basis." *Id.* When asked what circumstances were "causing the holdup" relating to the nonclinical manufacturing components of the process, J.R. 366, Erck referenced the fact that it "took a little longer" than expected to develop "a potency assay" that worked at each manufacturing site and reported that it had now done so:

> I'm happy to say we did. We've crossed that bridge. We're—we made a big breakthrough there and we're now racing towards validating everything and putting it into a package.

Id. Similarly, Erck closed the earnings call by stating, "I think we've eliminated all of the serious hurdles to getting – risk hurdles to getting to where we need to be to get an improved vaccine." J.R. 368.

As alleged in the Amended Complaint, however, at the time these statements were made, Novavax faced significant manufacturing concerns and thus was facing delays that prevented it from seeking regulatory approval anytime soon. Am. Compl. ¶¶ 74, 81. The Texas Facility had approximately four contamination incidents between December 2020 and March 2021, including three involving bacterial contamination caused by the reuse of a single-use plastic bag, the reuse of a single-use blade, and a leak in a bag used as part of a bioreactor. In March 2021, the FDA inspected the Texas Facility and issued a 52-page inspection memorandum identifying quality control, contamination, and purity issues and concluding that "[q]uality oversight over manufacturing and testing operations [was] sub-optimal." *Id.* ¶ 101. After this inspection, the Texas Facility's manufacturing process was shut down and remained shut down until at least September 2021.

In the same time frame, the North Carolina Facility similarly suffered contamination incidents that adversely impacted the vaccine's purity and potency levels. In April 2021, the FDA inspected the North Carolina Facility and issued an FDA Form 483 on April 21, 2021 in which it identified various quality-related problems, including inadequate control of microbial contamination. Based on these allegations, it is reasonable to infer that these issues had not been fully resolved at the time of the May 10, 2021 earnings call.

Notably, the Texas and North Carolina Facilities were critical to Novavax's development of the Vaccine. For example, on February 19, 2021, Trizzino testified to the House Committee on Energy and Commerce that the "antigen produced at the Fuji sites in North Carolina and Texas are a critical component of our US supply chain." *Id.* ¶ 269.

Under these circumstances, where Erck chose to speak about the timeline for regulatory approval and the manufacturing progress and effectively claimed that there were no remaining obstacles to obtaining approval and producing the vaccine, the failure to reference the contamination and purity issues at those facilities that were causing delays could constitute material omissions. *See Ottman*, 353 F.3d at 352; *Zak*, 780 F.3d at 610; *Singer*, 883 F.3d at 442. In particular, by explaining the delays by referencing the issue with the potency assay and reporting that it had been resolved, Erck's statement was misleading because he left out another important factor in the delay—the contamination issues at the Texas and North Carolina Facilities. Had the problems at the Texas and North Carolina Facilities been disclosed, that information would have "significantly altered the total mix of information" available to a reasonable investor because such an investor would have understood that Novavax's ability to obtain regulatory approval and produce the vaccine at scale was in jeopardy. *Paradise Wire*, 918 F.3d at 318. Plaintiffs have thus sufficiently alleged material omissions based on these statements.

C. June 14, 2021 Investor Call

Plaintiffs also allege materially false or misleading statements in a June 14, 2021 investor call intended to provide an update on Novavax's Phase III clinical trial results. In providing this update, Erck stated:

> So today is a great day for Novavax. This morning, we are talking about the exciting results of our PREVENT-19 Phase III study in the U.S. and Mexico. But this work follows a successful Phase III trial in the U.K., a successful Phase II trial in South Africa and a successful Phase I/II trial in the U.S. and Australia. These

> trials taught us a lot about our vaccine and from the early clinical data and even the preclinical work before that, we were encouraged about the potential of NVX-CoV2373 to play a significant role in combating the global COVID pandemic. **With each analysis, our trials proved that we are on the right track. And today, with safety and efficacy that are consistent across all studies, our PREVENT-19 results reaffirm our strong belief in 2373.**
>
> All of this work has been made possible by the participants who volunteered for our trials and the research and clinical staff who conducted the studies. We are grateful for all of these contributions.

Am. Compl. ¶ 134; J.R. 377.

Plaintiffs allege that the bolded statement was materially false or misleading because, at the time it was made, Novavax was experiencing a shortage of vaccine doses for clinical trials, which were causing trials to be delayed, and the above-described manufacturing problems at the Texas and North Carolina Facilities were ongoing. Read in context, however, this statement relates to the results of Novavax's clinical trials. Plaintiffs have not alleged that the clinical trial results did not show that the vaccine was safe and efficacious, and the fact that Novavax was experiencing shortages of vaccine doses for use in clinical trials, if true, does not render Erck's statements on the successful results of trials that were completed false or misleading. Likewise, because this statement relates to clinical trials and not manufacturing, the failure to disclose the manufacturing challenges as part of this statement did not render it false or misleading.

D. August 5, 2021 Reuters Interview

Plaintiffs further allege that Erck made a materially false or misleading statement in an August 5, 2021 interview with Reuters, specifically, "We appear to have got past (certain) supply issues and are now being able to produce at scale." Am. Compl. ¶ 147.

Plaintiffs have sufficiently alleged that this statement was false or misleading because the Amended Complaint asserts that at the time of Erck's statement, Novavax was "still unable to scale up production and manufacturing problems, such as not being able to meet the requisite

purity and potency levels for the Vaccine, experiencing contamination in critical manufacturing facilities, failing to successfully scale up production, and facing supply chain disruption." *Id.* ¶ 201. These general allegations are supported in part by the fact that at the time the statement was made, the Texas Facility, which was critical to the success of Novavax's efforts, was still shut down due to multiple incidents of bacterial contamination. Moreover, CW 6 has stated that supply chain issues, such as domestic supply constraints and difficulty obtaining certain materials, "were always a struggle." *Id.* ¶ 93. Similarly, CW 7 has stated that Novavax had difficulty procuring the components necessary to manufacture its vaccine, such as filters and resin used in the manufacturing process. CW 5 recalled that Novavax experienced difficulties in "acquiring the necessary number of different components used in the manufacturing process due to global supply chain issues." *Id.* ¶ 95. These issues impacted Novavax "for the duration of its vaccine development." *Id.* ¶ 94. Even if this statement could be deemed to be technically accurate, in that it arguably referenced different supply chain issues than those identified by the CWs and by some metric Novavax could be deemed to be producing at scale, once Erck chose to discuss supply chain and production issues, the failure to discuss the problems in those areas, particularly the shutdown of manufacturing at the Texas Facility, would be a material omission because it would have "significantly altered the total mix of information" available to a reasonable investor. *Paradise Wire*, 918 F.3d at 318; *see Ottman*, 353 F.3d at 352; *see Zak*, 780 F.3d at 610; *see Singer*, 883 F.3d at 442.

E. September 21, 2021 UNGA Conference

Plaintiffs also allege that, at a September 21, 2021 UNGA conference, Trizzino made materially false or misleading statements. On the call, a participant asked:

> There's a lot of concerns around transparency on the part of manufacturers. COVAX has recently raised this issue. And there have been reports that Novavax,

> and please correct me if I'm wrong, that your production capacity for 2022 is around 2 billion doses. But the question is, are all of those doses been allocated for already in advance?

J.R. 572.

In response, Trizzino stated:

> So it's another good question, right? **This transparency is important. And we've been extremely transparent across multiple fronts**. All of our clinical data has been shared very quickly. As you can imagine, being in the spotlight under a pandemic as a manufacturer and an innovator that has a highly effective vaccine, everybody wants to know when it's coming. So we're doing the best we can to keep everybody informed in an up-to-date fashion.
>
> We've talked about a global supply run rate of about 100 million doses before the end of this quarter and 150 million dose run rate capacity before the end of the year. Your number of 2 billion doses for next year is about right based upon what we would expect to be able to manufacture across the globe.

Id.

Plaintiffs allege that the bolded statements are false or materially misleading because Defendants were not transparent with respect to manufacturing problems related to contamination, purity, potency, scalability, and the supply chain. Beyond the fact that, considered in context, this statement does not relate to transparency on these particular topics, the Court finds that the vague claims that transparency is "important" and that Novavax has been "transparent across multiple fronts" constitute nonactionable puffery. *Id.* "The judiciary has long distinguished between mere puffing statements utilizing opinion and exaggeration to pitch a sale, on the one hand, and factual statements that constitute fraudulent misrepresentations, on the other." *Dunn v. Borta*,.369 F.3d 421, 431 (4th Cir. 2004). Puffery is defined as "loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available." *In re Cable & Wireless, PLC*, 321 F. Supp. 2d 749, 766–67 (E.D. Va. 2004) (collecting cases). The Fourth

Circuit has found that vague statements about the defendant's priorities and other non-factual boasting statements constitute puffery. *See In re Marriott Int'l, Inc.*, 31 F.4th 898, 902 n.1 (4th Cir. 2022) (finding that the defendant's statement that data security was "critically important" amounted to nonactionable puffery); *Longman v. Food Lion, Inc.*, 197 F.3d 675, 685 (4th Cir. 1999) (finding that the defendant's statements that its low prices and "clean and conveniently located stores [were] especially well suited to the demands of our customers" were nonactionable puffery that "reasonable investors could not have relied upon when deciding whether to buy stock"); *Raab*, 4 F.3d at 289 (finding that the defendant's statement that it was "poised to carry the growth and success of the prior year well into the future" constituted puffery). The highly general claims that Novavax has been extremely transparent and believes that transparency is important fall within this category of statements too vague and nonspecific to cause a reasonable investor to find them important to investment decisions and are therefore not actionable. *See Longman*, 197 F.3d at 685.

F. September 29, 2021 Healthcare Conference

Finally, the Plaintiffs assert that Trizzino made false or materially misleading statements at the Cantor Fitzgerald Global Healthcare Conference on September 29, 2021. At the conference, a participant asked:

> So why don't we talk a little bit about 2373 and the march to the market with that candidate? . . . If you could start, John, what is the official, if you will, guidance or goals with regard to emergency use authorizations and then manufacturing here in the near term?

J.R. 846. In response, Trizzino stated:

> So the latest kind of guidance we've been giving is that we work diligently over, as you can imagine, the last 6 or 9 months to kind of refine the final regulatory package that was being—that is planned to be submitted soon, and part of that was a couple of release assays that were particularly challenging given the construct of our vaccine that Greg mentioned before, and he can elaborate on that a little bit later.

> **But the combination of our recombinant protein nanoparticle, its nanoparticle structure, the particle structure of our Matrix adjuvant presented some challenges in those assays, which have now been resolved.** They've—both of those release assays have been validated. And though we're in the process of testing those assays against product prior to the submission of the final CMC package.

Am. Compl. ¶ 204; J.R. 846.

Plaintiffs allege that this statement is materially false and misleading because, at this time, Defendants had not yet resolved the manufacturing problems related to contamination, purity, potency, scalability, and the supply chain. Where the question specifically asked about the timing of an EUA application and the status of manufacturing, and Trizzino responded by identifying a single problem that explained the delays to date and that had by then been resolved, his answer could be deemed misleading because it gave the impression that there were no remaining challenges relating to manufacturing or the EUA timeline, such that the failure to disclose the contamination and other manufacturing problems could be deemed to be a material omission. *See Ottman*, 353 F.3d at 352; *Zak*, 780 F.3d at 610; *Singer*, 883 F.3d at 442.

The Court therefore finds that Plaintiffs have plausibly alleged false statements or omissions of material fact by Erck on May 10, 2021 and August 5, 2021 and by Trizzino on September 29, 2021.

IV. Scienter

Plaintiffs have also alleged that Erck and Trizzino made the false or misleading statements or omissions of material fact with scienter. The scienter element requires that a "plaintiff must prove that the defendant acted with 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 884 (4th Cir. 2014) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)). "At the pleading stage,"

allegations of "intentional or severely reckless conduct" suffice. *Id.* "In the § 10(b) context, a reckless act is one that is 'so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" *Id.* (quoting *Matrix Cap. Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 181 (4th Cir. 2009)).

Under the PSLRA's heightened pleading standards, a complaint alleging securities fraud must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). To allege fraud against a corporation, "the plaintiff must allege facts that support a strong inference of scienter with respect to at least one authorized agent of the corporation." *Yates*, 744 F.3d at 885 (quoting *Matrix Cap.*, 576 F.3d at 182). Inferences of scienter are to be given the "weight warranted by context and common sense" and must be weighed against the opposing inferences "drawn from the facts in their entirety." *Id.* (citations omitted). An inference of scienter is "strong" only where the inference is "at least as compelling as any opposing inference" of an innocent state of mind. *Id.* Where an inference of innocent or merely negligent action is more compelling than an inference of intentional or reckless conduct, a motion to dismiss will prevail. *Id.* Although an inference of scienter must be "strong in light of" alternative explanations, it need not be "irrefutable" or based on "smoking-gun" evidence. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

Under this standard, the fact that a defendant knowingly made an inaccurate statement—even a materially misleading one—is not, by itself, sufficient to support an inference of scienter. *Maguire Fin., LP v. PowerSecure Int'l, Inc.*, 876 F.3d 541, 548 (4th Cir. 2017) (declining to "stack inference on upon inference" and find scienter where the plaintiff "allege[d] facts that permit[ted]

an inference that" the defendant "knew his statement was false, and then" sought for the court to "infer from that inference that [he] acted with scienter"). However, where a plaintiff identifies "numerous allegedly misleading statements and omissions that were not caused by the use of imprecise language or the execution of a legitimate business decision," such allegations may support a strong inference of scienter. *Zak*, 780 F.3d at 610. *Compare id.* (finding scienter adequately pleaded where the plaintiff alleged that "defendants either knowingly or recklessly misled investors by failing to disclose critical information received from the FDA during the new drug application process, while releasing less damaging information that they knew was incomplete") *with Maguire Fin., LP*, 876 F.3d at 549 (declining to infer scienter from "an executive's use of a single *possibly ambiguous* word on a live analyst call that purportedly mischaracterized an agreement" relating to only "4.1% of the company's annual revenue").

In determining whether the plaintiff has sufficiently alleged scienter, the Court must view all of the allegations holistically. *Matrixx Initiatives*, 563 U.S. at 48. In evaluating the various indicia of scienter, the Court may question whether, "evaluating the complaint holistically, the combined allegations can do what their individual parts failed to do." *KBC Asset Mgmt. NV v. DXC Tech. Co.*, 19 F.4th 601, 613 (4th Cir. 2021).

In arguing that they have successfully pleaded facts supporting a strong inference of scienter, Plaintiffs rely on the allegations that (1) CWs have reported that Novavax was aware of the facts rendering statements false or misleading, and that based on their information it would be fair to infer that the officers making the statements were aware of those facts; (2) the FDA issued multiple warnings to Novavax that its manufacturing facilities and processes were not compliant with regulatory requirements; (3) the vaccine was core to Novavax's business and operations; and (4) stock sales in advance of the relevant public statements support an inference of scienter.

A. CWs

In seeking to establish scienter, Plaintiffs primarily rely on the statements of various CWs, consisting of employees of Novavax or FUJIFILM, including former managers and senior officials working at the Texas and North Carolina Facilities. In order for allegations by a CW to support an inference of scienter, the complaint must describe the CW with "sufficient particularity to support the probability that a person in the CW's position would possess the information alleged or, in the alternative, provide other evidence to support their allegations." *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 174 (4th Cir. 2007) (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 596 (7th Cir. 2006)).

The Amended Complaint contains facts from multiple CWs which "confirm and corroborate" that Novavax officials were made aware of the manufacturing problems at the Texas and North Carolina Facilities related to contamination, purity, potency, scalability, and the supply chain. Am. Compl. ¶¶ 275, 277. CW 5, the former Head of Technical Operations for Gene Therapy at FUJIFILM who had responsibility for technical operations that supported manufacturing at the Texas Facility, alleged that: (1) Novavax was required to be notified about contamination incidents at FUJIFILM within 24 to 48 hours of discovery; (2) two Novavax employees were onsite at the Texas Facility and communicated with the Texas Facility's Director of Manufacturing "every single day" regarding manufacturing and the results of quality checks, *id.* ¶ 278; (3) Novavax's onsite employees were notified about each contamination incident that occurred at the Texas Facility; (4) one Novavax onsite employee participated in the investigation into the contamination incidents and in phone calls and email communications with Novavax headquarters about the contaminations and resulting delays; and (5) the March 2021 contamination incident resulting in the shutdown of the Texas Facility was communicated to the Novavax onsite

employees, and the resulting investigation included "daily calls" with Novavax personnel at headquarters, *id.* ¶ 280. Likewise, CW 6, the former FUJIFILM Director of Manufacturing at the Texas Facility, alleged that: (1) Novavax placed rotating employees at the Texas Facility; and (2) CW 6 participated in Zoom calls "every day" with Novavax's onsite employees, a Novavax headquarters employee, and Novavax employees from different departments, such that Novavax employees "knew everything that we were doing." *Id.* ¶ 281.

CW 7, a former FUJIFILM Manager of Quality Assurance at the North Carolina Facility, made similar allegations about the contamination at the North Carolina Facility, including that: (1) any problems related to the North Carolina Facility were constantly communicated to Novavax; (2) Novavax had an employee onsite at the North Carolina Facility at least once a week; (3) all testing results from the North Carolina Facility were communicated to Novavax through a "batch record"; (4) when FUJIFILM changed the vaccine manufacturing materials because of certain supply chain problems, Novavax had teams of its own employees involved in any such modifications and was required to approve all such changes; and (5) Novavax was involved with "everything" and was "driving" the way in which FUJIFILM manufactured the product, and the level of Novavax's involvement was unlike anything she had previously encountered at FUJIFILM with other clients. *Id.* ¶ 282.

CWs also provided information supporting the conclusion that the information received by Novavax employees from the Texas Facility and the North Carolina Facility was communicated up to senior management at Novavax. First, CWs generally confirmed that Erck was personally and directly focused on issues relating to regulatory approval and progress on manufacturing. In particular, CW 2, a former Novavax Medical and Communications Publications Specialist, reported that Erck held company-wide meetings and Q&A sessions with Novavax employees to

discuss the regulatory process related to the Novavax Vaccine. CW 1, Novavax's Manager of Regulatory Affairs for Chemistry, Manufacturing, and Controls, has stated that during such sessions, Erck responded to employee concerns about Novavax's manufacturing capabilities.

Second, and more specifically, CW 4, the former Novavax Senior Director of Clinical Operations who was responsible for overseeing the company's U.K. clinical trials, reported that manufacturing issues were generally brought to the attention of Chief Medical Officer Filip Dubovsky, who in turn discussed the issues with Erck.

Considered together, the CWs' allegations demonstrate that information on the contamination and manufacturing problems flowed from the Texas and North Carolina Facilities to Novavax personnel working at those locations and at headquarters, that such information generally flowed through the Chief Medical Officer to Erck, and that Erck was generally knowledgeable about manufacturing issues. A CW report that the senior company official making public statements remained abreast of the relevant issues is probative on the issue of scienter. *See Cutler v. Kirchner*, 696 F. App'x 809, 815 (9th Cir. 2017) (finding that a CW's allegation that the defendant executives "kept abreast" of the progress of its new product including by participating in quarterly update meetings provided support for an inference of scienter). Likewise, a demonstration that the relevant information generally flowed to senior company officials making the public statements provides some evidence of scienter. *See Moshell v. Sasol Ltd.*, 481 F. Supp. 3d 280, 290 (S.D.N.Y. 2020) (finding that a CW's allegation that key information "would have gone to the company's Vice President, who in turn would have submitted an order to the senior executives" was among the facts supporting an inference of scienter); *Loritz v. Exide Tech.*, No. 2:13-cv-2607-SVW, 2014 WL 4058752, at *11–12 (C.D. Cal. Aug. 7, 2014) (finding that allegations of "an information chain . . . between plant level management and corporate

management" were among the facts supporting an inference of scienter). While the CWs do not allege that they personally provided specific problematic information to Erck, allegations of scienter need not provide "smoking-gun" evidence. *Inst. Inv. Grp. v. Avaya*, 564 F.3d 242, 268–69 (3d Cir. 2009) (rejecting the argument that CW allegations did not give rise to a strong inference of scienter because the plaintiffs did not point to a particular conversation in which the CW brought the issues in question to the defendants) (citing *Tellabs, Inc.*, 551 U.S. at 324). Thus, the Court finds these allegations probative on the issue of scienter. At the same time, because they provide only circumstantial evidence that Erck was aware of the information about contamination and other manufacturing problems, they are not alone sufficient to establish a strong inference of scienter.

B. FDA Findings

Plaintiffs also allege that the evidence of the FDA's actions relating to the Novavax Vaccine and Novavax's manufacturing plants supports an inference of scienter because Erck, Trizzino, and the other Defendants would necessarily have been aware of such regulatory findings. In *Zak*, the Fourth Circuit found sufficient information to support a strong inference of scienter based in part on the fact that the FDA had informed the company that it generally would approve the company's new drug based on data from two successful studies, but the defendants gave positive reassurances to investors even though there had been only one successful study. *Zak*, 780 F.3d at 609. Here, the FDA had issued an inspection memorandum to the Texas Facility and a Form 483 to the North Carolina Facility, both of which included a detailed list of the FDA's adverse findings at each facility, particularly findings relating to contamination. Significantly, the cGMP regulations required that "the responsible officials" of Novavax be notified in writing about any "reports of inspectional observations" issued by the FDA. Am. Compl. ¶ 107; 21 C.F.R. § 211.180(f). In fact, the FDA Texas Facility Report, on its face, specifically noted that FUJIFILM

had a requirement to inform Novavax of the findings, and CWs have stated that Novavax officials were so informed. The FDA also identified problems on other occasions, such as concerns regarding the stability of the vaccine batches, which were typically sent to the Novavax Director of Regulatory Affairs, and discrepancies in Novavax's potency levels.

Thus, Novavax was clearly informed of the FDA's findings. Even in the absence of direct evidence that Erck, Trizzino, and the other senior Novavax officers reviewed the FDA reports, the fact that Novavax was required by law to be informed of these FDA findings provides evidence in support of an inference of scienter. 21 C.F.R. § 211.180(f). Indeed, as one court has noted in a case in which the FDA issued Form 483s and a warning letter identifying manufacturing and quality control problems relating to a drug, it would be "absurd to think that the CEO and CFO of a pharmaceutical company would be unaware of the alleged substandard, noncompliant conditions" because "FDA warnings and failed inspections" are "crucial to a pharmaceutical company." *Mulligan v. Impax Laboratories, Inc.*, 36 F. Supp. 3d 942, 970 (N.D. Cal. 2014) (finding that the FDA's issuance of multiple Form 483s and warning letters supported an inference of scienter). The Court therefore finds that the FDA's issuance of the FDA Texas Facility Report and the Form 483 to Novavax provides additional evidence of scienter.

C. Core Operations

To establish scienter, Plaintiffs also rely in part on the fact that the Novavax Vaccine was core to Novavax's operations. Although not sufficient to establish scienter by itself, the fact that the subject of the alleged fraud was a core business or operation of the company is relevant to the analysis of scienter because under such circumstances it would be fair to infer that the company officers responsible for public statements were aware of facts relating to that activity. *Yates*, 744 F.3d at 890; *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West*

Holding Corp., 320 F.3d 920, 943 n.21 (9th Cir. 2003) (finding sufficient allegations of scienter based in part on the conclusion that it would be "absurd" to suggest that the Board of Directors would not discuss issues related to a Federal Aviation Administration investigation which could have resulted in substantial penalties); *see also Kiken v. Lumber Liquidators Holdings, Inc.*, 155 F. Supp. 3d 593, 606 (E.D. Va. 2015) (holding that "it is relevant to the Court's holistic analysis whether the alleged fraud dealt with core operations of the business, because high-ranking officers presumably know facts about the core operations of the company"). Here, it cannot be seriously disputed that the development of the Novavax Vaccine was a core operation of Novavax and critical to its long-term success. Although the development of vaccines is the core of Novavax's business, at the time of the relevant events, Novavax had never brought a successful vaccine candidate to market and thus, prior to the COVID-19 pandemic, was facing significant financial hardship. In fact, in 2019, Novavax sold all of its manufacturing facilities in order to avoid going out of business, and in January 2020, Novavax had only 150 employees and had only enough cash to survive another six months. It also risked being delisted from the NASDAQ stock exchange. As a result, once Novavax announced in February 2020 that it was seeking to develop a COVID-19 vaccine, that development became, as Trizzino stated in a February 19, 2021 report to the House Committee on Energy and Commerce, Novavax's "priority and singular goal." Am. Compl. ¶ 267. Because the development of the vaccine was so critical to Novavax's success, the Court finds that it was a core operation of Novavax, and that this fact makes it more plausible that Erck, Trizzino, and the other Novavax officers were aware of the facts underlying the allegedly false statements and material omissions. *See Yates*, 744 F.3d at 890 (stating that allegations of a particular segment's importance to the whole business are "relevant to the court's holistic analysis of scienter"); *see also In Re Iso Ray, Inc. Sec. Litig.*, 189 F. Supp. 3d 1057, 1078–80 (E.D. Wash.

2016) (finding that it would be "absurd" for the defendant to lack knowledge of the information underlying the fraud when it related to the company's only product that was critical to its success); *In Re Hi-Crush Partners L.P. Sec. Litig.*, No. 12 Civ. 8557(CM), 2013 WL 6233561, at *26 (S.D.N.Y. Dec. 2, 2013) (finding that the core operations doctrine supported scienter where the subject matter was "critical to the long term viability" of the company and to events "affecting a significant source of income").

D. Stock Sales

Finally, Plaintiffs allege that the timing and amount of sales of Novavax by Erck and Trizzino provide additional evidence of scienter. Allegations that a defendant engaged in insider trading can support an inference of scienter "if the timing and amount of a defendant's trading were unusual or suspicious." *Yates*, 744 F.3d at 890 (quoting *Teachers' Ret. Sys. of La.*, 477 F.3d at 184). In determining whether an insider's sales were unusual in scope, the Court may consider "the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved." *Id.*

On May 5, 2021 and May 7, 2021, prior to the May 10, 2021 investor call, Trizzino sold over 3,000 shares of Novavax stock for nearly $600,000. On May 10, 2021, Novavax announced that it was unlikely to seek an EUA from the FDA until the third quarter of 2021, after which the Novavax stock price fell 8.81 percent on May 10, 2021 and an additional 13.91 percent on May 11, 2021. By comparison, in May 2020, one year before, Trizzino sold no Novavax stock. More broadly, throughout the Class Period, Trizzino received more than $12 million from the sale of Novavax stock.

In July 2021, prior to the August 5, 2021 Reuters interview, Erck sold over 100,000 shares of Novavax stock for over $22.5 million. On August 5, 2021, Novavax further delayed its EUA

application, previously expected to occur in the third quarter of 2021, and reported that it expected to file it in the fourth quarter of 2021, after which the stock price dropped by 19.61 percent. By comparison, in July 2020, one year before, he sold no Novavax stock. More broadly, during the Class Period, Erck received $38.7 million from the sale of Novavax stock, as compared to only $4.5 million during the Control Period.

Particularly where the allegations support the inference that Erck and Trizzino timed at least one sale to take advantage of the fact that adverse information was soon to be disclosed, the facts relating to stock sales provide further support for an inference of scienter. *See Stevelman v. Alias Research Inc.*, 174 F.3d 79, 87 (2d Cir. 1999) (finding that evidence that a defendant sold large portions of his stockholdings gave rise to a strong inference of scienter because the sales were suspiciously timed and several officers made large sales); *In re Cabletron Sys., Inc.*, 311 F.3d 11, 39–40 (1st Cir. 2002) (finding that allegations that the defendants engaged in insider trading, taken together with other allegations of scienter, gave rise to a strong inference of scienter because of the timing of the sales and the substantial profit the defendant made); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 278 (3d Cir. 2006) (finding that allegations that the defendant engaged in insider trading gave rise to a strong inference of scienter because the timing of the sales was suspicious, the defendant sold over 30 percent of his holdings, the sales were not routine, and the profit was substantial). *Cf. Yates*, 744 F.3d at 890 (finding that, although the value of shares sold during the class period was higher than in previous years, the inference that the trades were innocent was stronger in part because the plaintiffs did not allege that the insiders timed the sales to take advantage of any particular disclosure).

Defendants counter that the stock trades were made pursuant to nondiscretionary trading plans pursuant to SEC Rule 10b5-1. As discussed above, the Court does not consider the additional

documentation relating to these sales submitted by Defendants. *See supra* part I; *see Zak*, 780 F.3d at 607. Even it did, the Court does not have information relating to when Erck or Trizzino entered into the trading plans or the specific terms of the plans. Without such information, the Court does not find that the alleged nondiscretionary trading plans negate the inference of scienter. *See KBC Asset Mgmt. NV*, 19 F.4th at 611 (holding that even with information on the existence of a 10b5-1 trading plans, the lack of evidence on when the defendants entered their plans prevented the court from concluding that the plans mitigated the "suggestion of motive" for the "suspicious trading"). Thus, the stock sales constitute additional evidence of scienter.

E. Holistic Analysis

Although each of the four categories of Plaintiffs' scienter evidence may be insufficient by itself to establish a strong inference of scienter, the Court must consider them together and assess the totality of the circumstances. *See id.* at 613 (stating that in evaluating the various indicia of scienter, the court evaluates the complaint holistically and determines whether all of the indicia of scienter support a strong inference of scienter, even if one indicator does not do so alone). Although the CW information intended to demonstrate that the adverse facts from the Texas and North Carolina Facilities flowed up the chain to Erck and the other Individual Defendants is imperfect, it is bolstered by the fact that the most significant information consisted of reports and determinations by the FDA which by law were required to be brought to the company's attention, which in turn strengthens the inference that it was conveyed to Erck and the other members of senior management. This inference is further advanced by the fact that the Novavax Vaccine was a core operation of Novavax and was, in fact, the entire focus of its business at that time. When these factors are combined with the sales by Erck and Trizzino of a substantial amount of Novavax stock just prior to announcements about Novavax's regulatory delays, the Court finds that the

allegations are collectively sufficient to support a strong inference of scienter and to conclude that the inference of an intent to deceive is at least as compelling as the competing inference. *See, e.g.*, *See City of Taylor Gen. Emp. Ret. Sys. v. Astec Indus.*, 29 F.4th 802, 813–14 (6th Cir. 2022) (finding a strong inference of scienter based on a holistic analysis including consideration of the defendant's personal involvement in the company's operations and suspicious stock sales); *Sapssov v. Health Mgmt. Assoc., Inc.*, 608 F. App'x 855, 861 (11th Cir. 2015) (finding that allegations of fraud relating to improper admission of Medicare patients supported a strong inference of scienter based on multiple factors, including the individual defendants' heavy involvement in the daily operations of company, the amount and widespread nature of the fraud, the allegations of witnesses in a whistleblower action, and an investigation by the United States Department of Health and Human Services, Office of the Inspector General); *KBC Asset Mgmt. NV v. 3D Sys. Corp.*, No. 15-cv-02393-MGL, 2016 WL 3981236, at *8 (D.S.C. July 25, 2016) (finding that the core operations theory, the defendants' executive-level positions, the defendants' intimate involvement in the operations of the business in question, and the defendants' stock scales, taken together, supported a strong inference of scienter); *In Re Genworth Fin. Inc. Sec. Litig.*, 103 F. Supp. 3d 759, 784–86 (E.D. Va. 2015) (finding that, in a case involving false reporting of financial results, the core operations theory, the defendants' executive positions and intimate involvement in relevant business processes, the fact that the defendants received personal financial benefits arising from the misrepresentations, and the magnitude of the understatement of necessary reserves, taken together, supported a strong inference of scienter).

Thus, because the Amended Complaint contains sufficient allegations relating to scienter, the Court concludes that Plaintiffs have stated plausible claims for relief based on the false statements or material omissions of fact identified above. The Court will grant the Motion as to

claims based on other statements or omissions and as to the claims against Glenn and Covino, because Plaintiffs have not sufficiently alleged that these Defendants knowingly made false or materially misleading statements or omissions to investors.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss will be GRANTED IN PART and DENIED IN PART. The Motion will be granted as to (1) all claims against Defendants Glenn and Covino; (2) the claims based on the alleged false statements or material omissions made on February 24, 2021, June 14, 2021, and September 21, 2021; and (3) the claims based on the alleged false statement on May 10, 2021 about the successful manufacture of Novavax's drug substance at commercial scale at each of its plants. The Motion will be otherwise denied. A separate Order shall issue.

Date: December 12, 2022

THEODORE D. CHUANG
United States District Judge